Remarks

Applicants have carefully reviewed the Office Action mailed Jan. 21, 2004. The drawings were objected to. Claims 1-11 and 13-17 were rejected under 35 U.S.C. 103(a). Claims 19, 20, 23, 25, 31, and 33 were rejected under 35 U.S.C. 102(e). Claims 26-30 were rejected under 35 U.S.C. 103. Claims 12, 18, 21, 22, 24 and 32 were indicated as allowable if rewritten in independent form. Claims 1-33 were, and remain, pending.

The drawings were objected to for failing to include reference numeral 112. A replacement Fig. 3 has been provided that includes reference numeral 112. The drawings were also objected to for failing to show a plurality of inflatable balloon members, as recited in originally filed claim 24. A new Figure 8 has been provided, illustrating a mask 320 having multiple inflatable balloon members 326. Figure 8 is identical to Figure 1, but having mask 320 rather than mask 20, and having multiple inflatable balloon members 346 in place of single inflatable member 46. Inflatable balloons 346 find support in originally filed claim 24 and on page 9, lines 19-21.

Claims 1-11 and 13-17 were rejected under 35 U.S.C. 103(a) over Sniadach (US 2003/0024533) in view of Kondur (US 4,580,556). The Office Action stated that Sniadach discloses a first aperture having controllably variable inside diameter (15). Kondur was said to disclose a first shaft member for placing an endotracheal tube. Claims 19, 20, 23, 25, 31, and 33 were rejected under 35 U.S.C. 102(e) as anticipated by Sniadach. The Office Action stated that Sniadach discloses an adjustable inside diameter and a controllably variable inside diameter. Claims 26-30 were rejected under 35 U.S.C. 103, also over Sniadach.

All independent claims recite a first aperture having either a "controllably variable inside diameter" or an "adjustable inside diameter." A controllably variable inside diameter and an

adjustable inside diameter are both discussed at length on page 9 of the present application. The controllably variable inside diameter and adjustable inside diameter are there contrasted with a distensible or elastically expandable inside diameter. As stated in the present specification, "The distensible apertures are not variable in diameter about an open unoccupied lumen, but require a shaft inserted through the membrane aperture to stretch the opening inside diameter about the inserted shaft." Thus, in the present specification, the recited limitations "controllably variable inside diameter" and "adjustable inside diameter" both disclaimed distensible openings which require a shaft inserted to change the inside diameter.

Sniadach discuses a "fenestrated opening 15." See paragraphs 46 and 47 and Figure 1. Applicants respectfully submit that Sniadach discusses a distensible opening rather than a controllably variable inside diameter or adjustable inside diameter, as these limitations have been defined for the present claim limitations. The significance of the controllably variable inside diameter seal is explained below.

Endotracheal tubes used to intubate the trachea come in different sizes. These range in diameter 2 mm to 10 mm. The controllably variable inside diameter seal of the present invention can accommodate any of these sizes without having to change the mask, and to provide an airtight seal. The user may start out with trying to intubate the patient's trachea with an 8 mm endotracheal tube and during the process of attempting to intubate the trachea discover that the size is too big for the patient. Then, what can be done is to deflate the diaphragm, remove the 8 mm tube and try a 7 mm tube. Once the diaphragm is inflated, the same airtight fit around the tube can be achieved as was present with the 8 mm tube. This same airtight fit is not possible with the fenestrated opening of Sniadach.

Also, the present invention mask creates no friction between the endotracheal tube and the mask diaphragm. In the present invention, as recited in the present claims, once the diaphragm is deflated, the endotracheal tube does not necessarily rub against the orifice inside walls and hence slides into the trachea much more easily. It is important to remember that during attempts at intubation, every second counts. The faster, smoother insertion of the endotracheal tube permits quick restoration of ventilation. Any needless delay in insertion of the endotracheal tube results in the patient being deprived of oxygen and could result in death. Most patients will suffer hypoxia after breath holding for about 30 seconds.

Furthermore, secretions and vomits in the mouth can easily be suctioned out from the mouth through a suction catheter after increasing the inside diameter of the orifice. It is much easier to suction the mouth clear of secretions during attempts at intubation, while providing the patient oxygen to breath, using a mask as recited in the present claims.

Applicants respectfully submit that neither Sniadach nor Kondur teach or suggest the limitations of the independent claims, claims 1, 19, and 31. As the dependent claims contain all imitations of the independent claims, applicants respectfully submit that claims 1-33 are now in condition for allowance.

Reconsideration of all pending claims is respectfully requested. If a telephone conference would further prosecution, please contact the undersigned attorney at (612) 492-7016.

Respectfully submitted,

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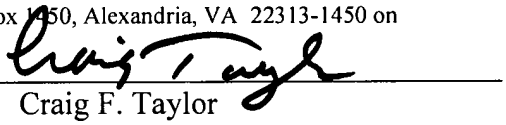
Apr. 21, 2004 

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Fig. 3

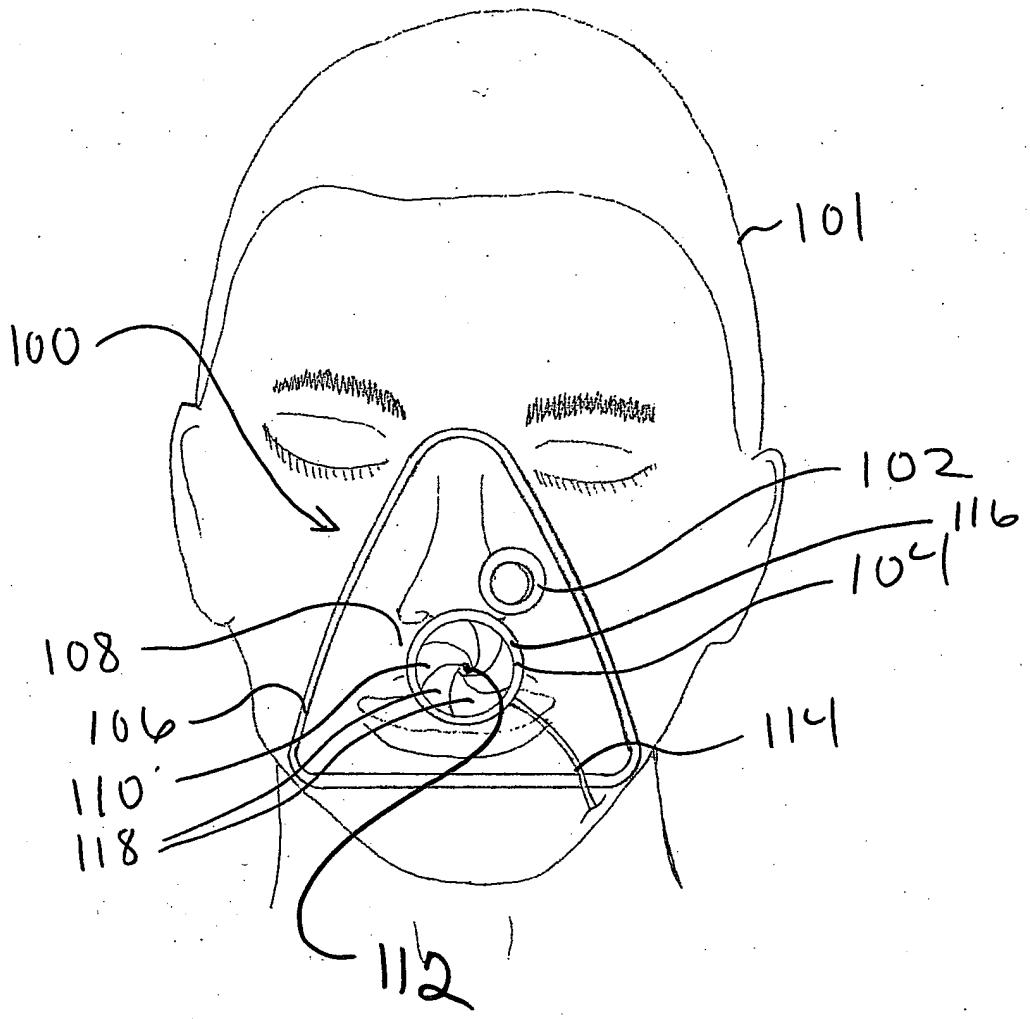

Fig. 8